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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/676,380      | 09/29/2000  | Andre T. Baron       | 07-277              | 1919             |

30058 7590 09/25/2008  
COHEN & GRIGSBY, P.C.  
625 LIBERTY AVENUE  
PITTSBURGH, PA 15222-3152

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| EXAMINER |
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BORGEEST, CHRISTINA M

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1649

|                   |               |
|-------------------|---------------|
| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

09/25/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPPatent@CohenLaw.com  
LPainePfister@CohenLaw.com

|                              |                                       |                                     |  |
|------------------------------|---------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/676,380  | <b>Applicant(s)</b><br>BARON ET AL. |  |
|                              | <b>Examiner</b><br>Christina Borgeest | <b>Art Unit</b><br>1649             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 18-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-31 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Amendment after Quayle Action*

The amendment filed 13 June 2008 is acknowledged. The amendment will not be entered since it raises new issues.

This application is in condition for allowance except for the following formal matters:

The declaration of Nita J. Maihle under 37 CFR 1.132 filed 13 June 2008 is insufficient to overcome the objection to the specification based upon the introduction of new matter as set forth at pages 3-4 in the last Office action for the reasons outlined below.

Applicants argue at p. 7, 1<sup>st</sup> paragraph, that regarding SEQ ID NO: 1 and SEQ ID NO: 3-6, that the Lys at position 540 should be Asn, and that this "is a conservative amino acid change that is not predicted to affect the function or structure of the proteins" and Applicant cites Ex Parte Maizel (recognizing "that single amino acid substitutions usually do not significantly alter biological activity of proteins").

Applicants argue at p. 7, 2<sup>nd</sup> paragraph, that regarding SEQ ID NO: 2, there are five independent discrepancies between the sequence listing of the application and the sequence submitted to GenBank, also and that Applicants were in possession of both nucleotide and polypeptide sequences at the time of filing.

Applicants argue at p. 8, 1<sup>st</sup> paragraph that position 1865 corresponds with a HindIII polymorphism and that positions 2394 and 2589 are likely sites of naturally occurring sequences and that because polymorphisms are naturally occurring, they are similar to the inherent characteristics supported in the case of Ex Parte Marsili. Finally they state that positions 706, 2394, 2435 and 2589 are likely to be typographical errors.

Note that according to Ex parte Maizel, 27 USPQ2d 1662 (Bd. Pat. App. & Int. 1992):

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“New matter” prohibition of 35 USC 112 plays important role in establishing filing date of application as prima facie date of invention, and thus it cannot be said that no harm is done to public when badly missequenced DNA is properly sequenced in specification prior to issue date of patent; patent laws do not permit insertion of additional descriptive matter subsequent to filing date in order to complete disclosure so as to conform specification's description of invention to statutory standard.’

Although Applicants argue that it states in Ex parte Maizel that it “appears to be recognized in the art that single amino acid substitutions usually do not significantly alter the biological activity of proteins,” it further states that “it is also recognized that additions or deletions of nucleotides in a DNA sequence can have drastic consequences...”

In addition, Ex parte Maizel further states:

[ 6 ] Appellants may be of the view that no harm is done to the public when a badly missequenced DNA is properly sequenced prior to the issue date of the patent. This is not always the case. The “new matter” prohibition of section 112 plays an important role in establishing the filing date of an application as the prima facie date of invention. In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973). On this point the Hawkins court quoted the concurring opinion in In re Argoudelis , 434 F.2d 1390, 1395, 168 USPQ 99, 104 (CCPA 1970) as follows:

[I]t is essential that there be no question that, at the time an application for patent is filed, the invention claimed therein is fully capable of being reduced to practice (i.e., that no technological problems, the resolution of which would require more than ordinary skill and reasonable time, remain in order to obtain an operative, useful embodiment).

Surely at the time of filing the instant application one of skill in the art, lacking a description of the amino acid structure of the protein, would have been unable to envisage and/or reduce to practice any “biologically functional” equivalent of the protein or the DNA coding for the equivalent. Accordingly, from a “scope of claim” viewpoint, appellants’ description of the invention at the time of filing the instant application, fell far short of what is now claimed.

Applicants have alleged in their remarks that one of skill in the art would be able to recognize and practice the invention, however, Ex parte Maizel is very clear about what is required to correct a sequence error, namely, 1) how was the error discovered

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and 2) how was the resequencing accomplished. In the instant case the originally disclosed material was resequenced. Providing a chain of events as to how the error was discovered and how the resequencing was accomplished "reflect[s] a desire to know whether the error would have been readily and easily detected by one skilled in the art."

The declaration is insufficient because it merely asserts that the errors are minor and one of skill in the art could recognize the invention. It does not matter whether the errors are minor. What is needed is a showing of how the error was discovered and how was the resequencing accomplished and that the resequencing was done on the originally disclosed material.

Applicant is required to correct this issue in the reply to this Office action.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 25 USPQ 74, 453 O.G. 213, (Comm'r Pat. 1935).

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 8:00am - 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

/Elizabeth C. Kemmerer/  
Primary Examiner, Art Unit 1646